The EMA Access to Documents Policy put to Trial. Case note on the cases T-718/15, T-235/15 and T-729/15

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Case T-718/15 PTC Therapeutics International Ltd v European Medicines Agency [2018] ECLI:EU:T:2018:66.

Case T-729/15 MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency [2018] ECLI:EU:T:2018:67.

Case T-235/15 Pari Pharma GmbH v European Medicines Agency [2018] ECLI:EU:T:2018:65.

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When it comes to the question of transparency and access to documents, the European Medicines Agency finds itself between a rock and a hard place. In the past the EMA has been criticized, for example by the European Ombudsman,[1] for not being transparent enough and excessively redacting documents requested especially with regard to potentially commercially confidential information. The pharma industry on the other hand, has now repeatedly taken the Agency to Court for granting third parties access to documents they submitted to the EMA, claiming an infringement of their rights to protection of commercially confidential information. While cases brought in 2013 by AbbVie and InterMune ended with an out of court settlement,[2] uncertainty remains regarding the scope of the protection of commercial interests against publication under Article 4(2) of Regulation 1049/2011 ('Transparency Regulation').

Article 4(2) of Regulation 1049/2011 forms an exception to the right of access to documents for specific reasons, such as 'commercial interests of a natural or legal person, including intellectual property', without defining these protected commercial interests further. Therefore, as the EMA has to apply the Transparency Regulation,[3] the Agency was left to define the scope of this exception in its own access to documents policy,[4] exposing it to the criticism of being either too transparent or too protective of commercial interest.

This apparently difficult balance between transparency as a core value of European law, enshrined in Article 15 TFEU, and the protection of commercially sensitive information, is by no means a challenge that is unique to the pharmaceutical sector, as the debate surrounding access to documents for the glyphosate re-authorization shows.[5] However, three cases ruled by the General Court in February have now clarified some questions on the balance between transparency and commercially confidential information. It should be noted that in the *PTC case* and the *Intervet case* appeals have been filed.

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1 See eg European Ombudsman, 'Decision of the European Ombudsman closing his inquiry into complaint 2560/2007/BEH against the European Medicines Agency' (November 2010); European Ombudsman, 'Decision on own-initiative inquiry OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of a medicinal product' (June 2016). It should be noted in this regard, that in recent cases the Ombudsman has taken a very positive view of the current EMA access to documents policy and the proactive publication of clinical trials, see European Ombudsman, 'Decision in case 1602/2016/JAS on the European Medicines Agency's handling of an access to document request related to clinical study report' (February 2018).

2 The General Court had annulled the interim measures which stopped the EMA from releasing the documents in question: Case C-390/13 P(R) *EMA v InterMune UK and Others* [2013] ECLI:EU:C:2013:795; C-389/13 P(R) EMA v AbbVie [2013] ECLI:EU:C:2013:794.

3 Art 73 of Regulation (EC) No 726/2004 foresees that Regulation (EC) No 1049/2001 applies to the Agency.

4 Currently applicable EMA access to documents policy: EMA, 'European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)' (2010) EMA/110196/2006.

5 In a previous issue of the EPLR, Giulia Schneider discussed this balance: Giulia Schneider, 'A Transparency Challenge: Can Commercial Confidentiality In Clinical Trials Data Be Overcome?' (2018) European Pharmaceutical Law Review 2(1), 3-18. For a detailed account of the debate surrounding Glyphosate see: E Korkea-aho and P Leino, 'Who owns the information held by EU Agencies? Weed killers, commercially sensitive information and transparent and participatory governance' (2017) Common Market Law Review 54 (4) 1059 -1092.

I. The Facts and Dispute in the Main Proceedings

In all three cases at hand, access to documents request had been addressed to the European Medicines Agency by a competitor company, requesting access to documents submitted to the EMA by another company - a third party in terms of the access to documents request - in the course of a marketing authorization procedure.

In the *PTC Therapeutics case* (T-718/15) the document concerned was a clinical study report submitted in the marketing authorization procedure for Translarna. While in the *MSD Animal Health and Intervet case* (T-729/15) a competitor requested access to toxicology tests submitted in the course of the marketing authorization procedure for the veterinary medicine Bravecto.

In the *Pari Pharma case* (T-235/15) the factual background is a bit more complex. The access to documents request concerned similarity and superiority reports with regard to an orphan medicinal product. In the case at hand, Novartis was the holder of a marketing authorization for TOBI as well as the orphan medicinal product TOBI podhaler, the orphan status of the latter being based on the significant benefits to the patients when compared to the existing treatment. Pari Pharma requested a marketing authorization for Vantobra with the same therapeutic indication as TOBI podhaler. Due to the orphan status of TOBI podhaler, a marketing authorization was only granted where similarity and clinical superiority of Vantobra could be shown. Vantobra was found to fulfil these conditions and was granted marketing authorization. The application was a hybrid application under Article 10(3), relying partially on documentation provided for TOBI. In the access to documents request Novartis asked for access to the marketing authorization report of Vantobra. Novartis had challenged the Vantobra marketing authorization.

The core question the EMA had to decide upon when receiving the access to documents requests was the applicability of the exception in Article 4(2) of the Transparency Regulation:

'The institutions shall refuse access to a document where disclosure would undermine the protection of: (...) commercial interests of a natural or legal person, including intellectual property (...) unless there is an overriding public interest in disclosure.'

Moreover, the exception in Article 4(3) applicable to documents in an un-finished procedure within an EU institution could also have been relevant, as for example in the *PTC case* where the product to which the documents related had been granted a conditional marketing authorization.

In all of these cases, upon receipt of the request for access to documents, the EMA had informed the companies which had originally submitted the documents (the 'third parties' in the access to documents procedure) of the access requests in accordance with its access to documents policy (Policy 0043).[6] When the EMA receives such access to documents request, Article 4(4) of the Transparency Regulation prescribes that the third party has to be consulted on the applicability of the exceptions to access, unless it is already clear for the institution that the document will be disclosed or will definitely not be disclosed. If the applicability or non-applicability of an exception is not obvious to the Agency, the company that submitted the document in the first place will be consulted, which usually includes being allowed to submit a redacted version.[7] The request not to disclose by the third party does not bind the agency, but in case the EMA will publish against the will of the third party, the third party will be notified of this before, with mention of the option for remedies.[8]

In the cases at hand, the EMA and the companies which had submitted the documents in question disagreed about the necessity and extent of redactions. This led to interim relief procedures in all three cases, in which the General Court suspended the EMA's decisions to disclose the documents in question.[9]

6 EMA, 'European Medicines Agency policy on access to documents (related to medicinal products for human and veterinary use)' (2010) EMA/110196/2006.

7 ibid 4-5; EMA, Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMA documents, Management Board meeting 19 December 2006, EMEA/MB/203359/2006 Rev 1 Adopted, art 8.

8 Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents, Management Board meeting 19 December 2006, EMEA/MB/203359/2006 Rev 1 Adopted, art 8(7).

9 Case T-235/15 *Pari Pharma v EMA* [2015] ECLI:EU:T:2015:587 and *Pari Pharma v EMA* [2016] ECLI:EU:T:2016:309; T-718/15 *PTC Therapeutics International v EMA* [2016] ECLI:EU:T:2016:425; T-729/15 *MSD Animal Health Innovation and Intervet international v EMA* [2016] ECLI:EU:T:2016:435.

The cases on the merits of these claims in front the General Court all dealt with a similar set of arguments. This case note will focus on the following claims:

- the documents in question are protected by Article 4(2) or (3) of Regulation No 1049/2001 pursuant to a general presumption of confidentiality;
- the documents in question are in their entirety commercially confidential information and are protected by Article 4(2) or (3) of Regulation No 1049/2001;
- parts of documents in question are commercially confidential information protected by Article 4(2) or (3) of Regulation No 1049/2001.

II. Judgment of the Court

1. Are the Documents in Question Protected by Article 4(2) or (3) of Regulation No 1049/2001 Pursuant to a General Presumption of Confidentiality?

The Court decided to first deal with the question of whether documents submitted in the context of a marketing authorization procedure, and essentially the whole Committee report, could benefit from a general presumption of confidentiality based on the protection of commercial interests in Article 4(2) or 4(3) of Regulation No 1049/2001. Pari Pharma for example argued that: '(...) protection of confidentiality should not only extend to the parts of the reports containing the most sensitive confidential information, but to the reports as such, because the most sensitive parts are integrated in a line of arguments which include matters relating to its proprietary strategy, and which form with other public elements of the reports an inseparable whole with economic value.'[10]

However, such a presumption of confidentiality would constitute a considerable interference with the principle of widest possible access to documents enshrined in the Transparency Regulation. Therefore, it is not surprising that according to the Court such an exemption will have to be narrowly construed. The Court, assessing previous cases, where such a general presumption of confidentiality for certain types of documents had been accepted, however, concluded that all of these categories of documents awarded a general presumption of confidentiality were part of an ongoing administrative or judicial procedure.[11] As the marketing authorization procedures of the respective products for which the access to documents was requested in the three cases were concluded, they could not avail themselves of the exception of ongoing administrative procedures.[12] The fact that in the *PTC case* the marketing authorization granted was a conditional marketing authorization did not matter in this regard.[13] The Court ruled in all three cases that once the administrative proceedings of a marketing authorization application have been finalized, the reports drawn up by the Agencies' scientific committees, containing all the documents concerned in the cases, are not subject to a general presumption of confidentiality.

In this regard, the Court also specifically refused an argument based on Article 39 of the TRIPS agreement. In the *Intervet case* and the *PTC case* the applicants argued that the documents are covered by a presumption of confidentiality throughout the period of data exclusivity or market exclusivity of orphan medicinal products, to prevent third parties from submitting this data with a new marketing authorization application. The Court had already stated that a possible reuse of the data concerned 'does not, in itself, constitute a ground to consider that the information is confidential', but that commercial confidentiality can and has to be proven for specific parts of the document.[14] According to the Court, also the applicability of Article 39(2) and (3) of the TRIPS Agreement do not lead to a presumption of confidentially during the data exclusivity period or the market exclusivity period grated to orphan medicinal products.[15] The Court in this regard implies that the European framework under Regulation 1049/2001 and 736/2004 sufficiently protects the data against unfair commercial use in the sense of the TRIPS

10 Case T-235/15 *Pari Pharma GmbH v European Medicines Agency* [2018] ECLI:EU:T:2018:65, para 36.

11 ibid, para 46.

12 ibid, para 57.

13 Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency* [2018] ECLI:EU:T:2018:66, para 74.

14 Case T-729/15 *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency* [2018] ECLI:EU:T:2018:67, para 46.

15 ibid, para 50; Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency* [2018] ECLI:EU:T:2018:66, para 64.

agreement.[16] In this regard, it should also be mentioned that the Court rejected an argument based on the possibility that data could be used in third countries to obtain marketing authorizations. The Court argued that as sensitive data such as the method for drug concentration measurement do remain confidential, no proof was provided that the use of the data in third countries is actually a risk.[17]

As all arguments in this claim failed, a general presumption of confidentiality for committee reports and all contained documents does not exist once the marketing authorization procedure is finalized.

2. Are the Documents in Question in their Entirety Commercially Confidential Information and subject to the exception under Article 4(2) or (3) of Regulation No 1049/2001?

Although, in the absence of a general presumption of confidentiality, the EMA will thus have to carry out an individual assessment of each document to which access is requested, the documents in question could still be commercially sensitive in their entirety. However, none of the applicants could convince the Court in this regard.

In principle, the Court did not exclude that the whole report could constitute commercially sensitive information. However, this would have to be specifically proven. The bottom line of the Courts approach is best to be explained by a quote from the PTC case:

> 'Consequently, in order to be able to claim confidential treatment in respect of the entire report at issue, it is for the applicant to show that the assembly of the publicly-accessible data together with the data which is not publicly accessible constitutes a commercially sensitive item of data whose disclosure would undermine its commercial interests. The assertion that 'the whole is more than the sum of its parts' is too vague to show that that assembly of information could produce the consequences alleged. It was all the more necessary to adduce precise and proper explanations since, as has been pointed out in paragraph 80 above, the exceptions provided for in Article 4 of Regulation No 1049/2001 derogate from the principle that the public should have the widest possible access to the documents and must therefore be interpreted and applied strictly.'[18]

Thus, where the entirety of a document should benefit from the exception under Article 4 of the Transparency Regulation, the congregation of the (non-protected) information as such must have commercial value.

3. Are Parts of Documents in Question Commercially Confidential Information Protected by Article 4(2) or (3) of Regulation No 1049/2001?

As the arguments for the applicability of the exceptions for the entirety of the reports failed, the applicants argued for protection of parts of the documents in question. Again, in all three cases the respective arguments failed. Rather than looking at the individual reasons for denying the applicants the protection they sought under Article 4(2) and (3) of the Transparency Regulation, the following section will examine how the Court constructs the requirements of the Article to exempt commercially sensitive information from the general rule that access should be granted.

First of all, relying on case law such as case T-437/08 *Hydorgene Peroxide v Commission* and case T-516/11 *MasterCard and others v Commission*, the Court makes clear that commercially sensitive information is not simply any information about a company or its business relations,[19] the hurdle to command protection from publication under Article 4(2) of the Transparency Regulation is higher. According to the Court, what is required for a correct application of the exception is that the access to that document could 'specifically and actually undermine the

16 Case T-729/15 *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency* [2018] ECLI:EU:T:2018:67, para 51; Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency* [2018] ECLI:EU:T:2018:66, para 65; See also in this regard, Giulia Schneider, 'A Transparency Challenge: Can Commercial Confidentiality In Clinical Trials Data Be Overcome?' (2018) European Pharmaceutical Law Review 2(1), 3-18.

17 Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency* [2018] ECLI:EU:T:2018:66, para 94.

18 ibid para 89.

19 Case T-235/15 *Pari Pharma GmbH v European Medicines Agency* [2018] ECLI:EU:T:2018:65, para 70.

interest protected by an exception laid down in that article'.[20] This means that, 'it must be shown that the documents at issue contain elements which may, if disclosed, seriously undermine the commercial interest of a legal person',[21] which includes business strategies or 'information particular to that undertaking which reveals its expertise'.[22]

Merely compiling publicly available studies or scientific reports will not satisfy this hurdle, whereas adding value to such data by drawing novel scientific conclusions or developing an inventive strategy can satisfy the conditions.[23] An argument that the Court was quite clear about in these cases was that the documents in question failed to show a know-how or novelty in approach regarding how the studies in question were conducted, regarding 'models, assays or methodologies'.[24] In the *Intervet case*, for example, the applicant claimed that the study reports in question would be commercially sensitive as they are based on significant regulatory knowledge and strategic approaches to innovative study design.[25] The EMA countered this argument by referring to the EU and international guidelines and recommendations that form the basis of the safety tests.[26] According to the Court, 'the applicants have not put forward any scientific evidence to show that the reports contain any elements that are unique and important for informing their overall strategy and development programme.'[27] It should also be mentioned that the significant costs involved in actually conducting the studies did not satisfy the Court, as these costs are incurred by all pharmaceutical undertakings.[28]

III. Comment

Although the outcome of these rulings will certainly not be welcomed by everyone, at least they provide some clarity in a situation of uncertainty that has kept the pharmaceutical industry as well as the EMA busy since several years.

1. Do the Judgements Clarify the Scope of Commercial Confidentiality in Terms of Article 4(2) and (3) of the Transparency Regulation?

The Court approached the question of commercially sensitive information from a more abstract standpoint. It did not provide too much guidance on what actually constitutes commercially confidential information in the marketing authorization documentation, but focused on requiring that each and every individual claim of commercially sensitive information of a document or its parts has to be well substantiated with very concrete proof in order to successfully avail itself of the application of the exception in Article 4(2) and (3) of the Transparency Regulation. What these judgements have made very clear, is that the age of broad and unsubstantiated claims to commercial confidentiality is over. While the Court does not generally exclude protection under the exception for any of the documents in question, it has made very clear that any application of this exception to the general rule of transparency has to be duly substantiated by scientific or economic arguments of novelty, innovation and unique expertise.

Reading the judgments, one cannot help but wonder what will still fall under the protection of commercially confidential information, as it is quite clear that the hurdle to prove commercial confidentiality is quite high. The judgements do not provide a clear list of commercially confidential information, unlike what the EMA and Heads of Medicines Agencies (HMA) have provided in their respective policies,[29] but focusses on an obligation to prove novelty and uniqueness to invoke the exception. What this means in practice is that the dispute between marketing authorization holders and the Agency will have to con-

20 ibid para 69.

21 ibid para 71.

22 ibid.

23 ibid para 77.

24 Case T-718/15 *PTC Therapeutics International Ltd v European Medicines Agency* [2018] ECLI:EU:T:2018:66, para 90.

25 Case T-729/15 *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency* [2018] ECLI:EU:T:2018:67, para 59.

26 ibid paras 72 and 73.

27 ibid para 75.

28 ibid para 89.

29 HMA/EMA, 'Guidance Document on the Identification of commercially confidential information and personal data within the structure of the marketing authorization (MA) application – Release of information after the granting of a marketing authorization' <http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf> accessed 21 April 2018; EMA, 'Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA Documents' (April 2007) EMEA/45422/2006.

tinue, until the contours of sufficient prove for the requirements developed for the applicability of the exception are clearer.

2. What does this Mean for the Clinical Trials Publication under EMA policy 0070 and the Clinical Trials Regulation?

The potential conflict between transparency and protection of commercial confidentiality is not only inherent in access to document request under the Transparency Regulation, but is also encompassed in the proactive clinical trials data publication under EMA policy 0070,[30] as well as the Clinical Trials Regulation.[31] In this regard, also Article 81(4)(b) of the Clinical Trials Regulation contains an exception to public access to clinical trials data on the basis of protection of commercially confidential information in absence of an overriding reason of public interest in disclosure.

An advice from the clinical trial advisory group on legal aspects to the European Medicines from 2013 shows, the arguments pro and counter the proactive publication of clinical trial data by the agency are made along the same lines as the arguments in the access to documents cases at hand.[32] The General Court, although ruling on access to documents cases, has thereby confirmed the arguments for proactive publication of clinical trials data. In policy 0070, the factors on which the EMA decides on the commercial sensitive of certain data are: 'the nature of the product concerned, the competitive situation of the therapeutic market in question, the approval status in other jurisdictions, the novelty of the clinical development, and new developments by the same company.'[33] This seems to be largely congruent with the Court rulings at hand and might already provide some indications with regard to how pharma companies might approach evidencing commercial sensitive information.

However, similar to the access to documents request, we will probably continue to see debates between the Agency and the industry about the concrete application of the requirements of proof of commercial sensitivity also with regard to the proactive publication of clinical trials data. The proactive publication process however, through the sheer mass of data, will at first mean a labor-intensive process on the side of both the Agency and the industry. However, it will also mean that further clarity on the EMAs stance on what is commercially sensitive will develop quicker.

3. Transparency in Pharma: A Normative Choice

In the context of the debate surrounding transparency of clinical trials data and industry originating documents in general, many arguments have been raised in favor and against publication.[34] In all three cases at hand here, the access to documents request was filed by competitor companies. One might legitimately ask if this serves the promotion of public health. Therefore, it makes sense to take a closer look at the rationale of transparency in this context.

According to the EMA, as far as the proactive publication of clinical trial data is concerned, the objectives of the policy are the facilitation of public scrutiny as well as 'to make medicine development more efficient by establishing a level playing field that allows all medicine developers to learn from past successes and failures', both for the benefit of public health.[35] Thus, the argument is twofold: transparency of the data used in the marketing authorization process is as much concerned with the public control over the EMA decision-making process as it is with the promotion of health innovation.

If one were only concerned about the effect of transparency on the development of new pharmaceuticals, the debate between pro- and counter- argu-

30 EMA, 'European Medicines Agency policy on publication of clinical data for medicinal products for human use, POLICY/0070' (October 2014) EMA/240810/2013.

31 Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC [2014] OJ L 158, 1–76.

32 Clinical trial Advisory Group on Legal aspects (CAG5), 'Final advice to the European Medicines Agency from the clinical trial advisory group on legal aspects' (April 2013) <http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/04/WC500142857.pdf> accessed 10 May 2018.

33 EMA, 'European Medicines Agency policy on publication of clinical data for medicinal products for human use, POLICY/0070' (October 2014) EMA/240810/2013, 4.2.2.1.

34 See eg, H G Eichler amd E Abadie, A Breckenridge, H Leufkens and G Rasi, 'Open Clinical Trial Data for All? A View from Regulators' (2012) PLoS Medicine 9(4).

35 EMA, 'European Medicines Agency policy on publication of clinical data for medicinal products for human use, POLICY/0070' (October 2014) EMA/240810/2013, 4.1.

ments towards publication seems to be running into a deadlock. In the end, only time can tell whether the clinical trial data transparency actually impedes innovation by preventing companies from reaping the benefits of their investments, or if it actually fosters innovation by granting easier access to clinical trials data to inspire the development of novel products. It remains to been seen if the costs involved by the publication and redaction process incurred by both the industry and the Agency will pay off in terms of gains in public health.

However, the EMA, the EU legislator and now also the General Court have made a normative choice in favor of transparency. The Court's vision of the underlying normative reasoning in favor of transparency becomes clear in the judgements. In the *Pari Pharma case* the Court states: 'In the field of medicinal products, that requirement of transparency is justified by the need for supervision of the EMA's activities and, in particular, by healthcare and research professionals, (...).'[36] Moreover, in the *Intervet case* the Court refers to the broader logic of transparency in EU institutional law: 'it should be pointed out that the transparency of the process followed by the EMA and the possibility to obtain access to the documents used by that agency's experts to prepare their scientific assessment contribute to such an authority acquiring greater legitimacy in the eyes of the persons to whom that measure is addressed and to increasing their confidence in that authority and to ensuring the authority is more accountable to citizens in a democratic system.'[37]

So, although the protection of public health through enabling peer review of published data and further use of these data to foster health innovation might be driving forces behind the EMAs ambitious clinical trials publication policy, transparency is actually more than that. It is a normative choice that is enshrined in EU administrative and institutional law and vigorously promoted by several stakeholders in the last years. This will be very difficult to argue against.

In this regard, it is also interesting to note that the judgements leave the question of what constitutes an 'overriding public interest' unanswered. Even if information is deemed commercially confidential under Article 4(2) of the Transparency Regulation, it might still be disclosed under an overriding reason of public interest. It could be argued that even if a company would pass the hurdle of proving commercial confidentiality under Article 4(2) of the Transparency Regulation, the second limb of that exception might still lead to publication as the normative choice in favor of transparency also might lead to a broadly construed 'overriding public interest' and thus disclosure of commercially sensitive information. However, the Court in its access to documents case law has so far not been very keen on recognizing an overriding public interest which would allow for disclosure of information that would otherwise benefit from a publication exemption.[38] For example in *C-612/13P Client Earth*, where ClientEarth argued that the principles of democracy and transparency would lead to an overriding public interest of citizens being informed about the compatibility of national law with EU environmental law, the Court ruled that 'considerations as general as those relied on by ClientEarth are not capable of demonstrating that the principles of transparency and democracy raised (...) issues of particularly pressing concern which could have prevailed over the reasons justifying the refusal to disclose.'[39]

In the cases at hand, as the information was not deemed commercially sensitive, this clause was not applicable and the Court only hinted at the fact that pharmacovigilance could be an overriding public interest for publication.[40] The Ombudsman took a quite strong position on the matter, arguing that '... in relation to the overriding public interest test, (...) EMA should consider that there is always a compelling reason for information to be disclosed, where information at issue has clinical value to clinicians (as regards understanding the safety and efficacy of a product for uses to which it is put, including off-label uses). Such information should always be disclosed even where disclosure risks undermining a company's commercial interests. In short, public

36 Case T-235/15 *Pari Pharma GmbH v European Medicines Agency* [2018] ECLI:EU:T:2018:65, para 99.

37 Case T-729/15 *MSD Animal Health Innovation GmbH and Intervet international BV v European Medicines Agency* [2018] ECLI:EU:T:2018:67, para 5.

38 See, D Curtin and P Leino-Sandberg, 'Openness, Transparency and the Right of Access to Documents in the EU: In-depth analysis' (2016) Report for the Petitions Committee, European Parliament <http://www.europarl.europa.eu/thinktank/en/document.html?reference=IPOL_IDA(2016)556973> accessed 23 May 2018.

39 Case C-612/13P *ClientEarth v European Commission* [2015] ECLI:EU:C:2015:486, para 93.

40 Case T-235/15 *Pari Pharma GmbH v European Medicines Agency* [2018] ECLI:EU:T:2018:65, para 101.

health should always trump commercial interests.'[41] It remains to be seen how far the scope of overriding public interests might reach in the context of pharmaceutical data. Following these cases, this question remains ambiguous and in this regard further clarification is required.

41 European Ombudsman, 'Decision on own-initiative inquiry OI/3/2014/FOR concerning the partial refusal of the European Medicines Agency to give public access to studies related to the approval of a medicinal product' (June 2016) para 74.